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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,109	07/01/2003	Richard C. Ewers	USGINZ02110	3376

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EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,109	EWERS ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-10,12,46-56 and 58-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8-10,12,46-56 and 58-60* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see Remarks, filed June 2, 2009, with respect to the rejection(s) of claim(s) 1-5, 8-10, 12, 46-56 and 58-60 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 8-10, 46, 49-51, 53, 55, 59 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Hussein et al (U.S. Patent No. 5,971,993).

With respect to **claim 1:** Hussein discloses a delivery catheter. With regard to the limitation "for a gastric reduction system", the delivery catheter disclosed by Hussein meets all of the structural limitations of claim 1 and therefore is fully functional for use in a gastric reduction system. The delivery catheter comprises the following: an elongate torqueable and flexible tube 79 having a back end and a front end (Fig. 12, Col. 5, lines 53-56) inasmuch as the tube is able to be inserted and navigated from an incision to a surgical site in the heart wall; a needle 70 translatably disposed within the tube inasmuch as it is removably coupled to outer sheath 71

which holds tube 79 stationary while the needle is decoupled, with the needle having a penetrating tip 73 (Fig. 12, Col. 5, lines 44-57); at least one anchor 18 as part of a myocardial implant translatably disposed within the needle on tip 77 between the handle 72 and needle tip 73, and moveable out of the penetrating tip 73 of the needle into the heart wall tissue (Col. 5, lines 61-64) and a coil, namely the body 16 of the implant, on a front end of a shaft 77 that is translatably disposed within a lumen in said tube, said coil 21 being extendible out of the front end of the tube so as to be anchored in the heart wall tissue. (Fig. 4, Col. 3, lines 63-65)

With respect to **claim 8:** The coil 16 disclosed by Hussein necessarily includes a sharpened distal tip to facilitate tissue penetration. (Col. 4, lines 13-18)

With respect to **claim 9:**: The phrase “plurality of coils” is interpreted in light of the specification, i.e. a plurality of turns or revolutions the coil body defines. The coil 16 comprises a plurality of coils/turns that form a central opening for the passage of the needle 70, specifically tip 77. (Figs. 4, 12,13A, Col. 4, lines 13-17, Col. 5, lines 42-64)

With respect to **claim 10:** The coil 16 and needle 70 are substantially coaxial. (Figs. 4,12,13A)

With respect to **claim 46:** Hussein discloses a catheter comprising the following: a flexible tube 79 having a front end adjacent needle tip 73 and a back end adjacent handle 78 (Fig. 12) inasmuch as the tube is able to be inserted and navigated from an incision to a surgical site in the heart; a needle 70 within the tube 79 and having a tip 73 extendible out of the front end of the tube via decoupling of the needle tip from the rest of the assembly: at least one anchor in the form of a myocardial implant positioned within the flexible tube 79 and moveable out of the

flexible tube during a surgical procedure into heart wall tissue; a suture 65 connected to one or more of the anchors, and with the suture in the form of anchor wire 65 being continuous with the coil 16 of the implant and thus extending within the tube towards the back end of tube 79; and a coil 16 on a front end of a shaft, needle tip 77, that is translatably disposed within a lumen in said tube by virtue of being able to be pulled out of the tube 79 upon decoupling of the needle tip assembly from the rest of needle 70, said coil 16 as part of the anchor/implant being extendible out of the front end of the tube upon insertion into heart wall tissue.

With respect to **claim 49:** The coil 16 disclosed by Hussein necessarily includes a sharpened distal tip to facilitate tissue penetration. (Col. 4, lines 13-18)

With respect to **claim 50:** The needle 70 disclosed by Hussein has a penetrating tip 73 adjacent to the front end of the flexible tube 79. (Fig. 12)

With respect to **claim 51:** The needle 70 disclosed by Hussein is positioned to extend out of the front end of the flexible tube and through the coil 16/87. (Fig. 13A)

With respect to **claim 53:** The needle 70 disclosed by Hussein has a non-coring tip 73.

With respect to **claim 55:** Hussein discloses a catheter comprising the following: a flexible and torqueable tube 79 having a front end and a back end inasmuch as the tube is able to be inserted and navigated from an incision to a surgical site in the heart; a needle 70 within the tube and having a piercing tip 73 extendible out of the front end of the tube; one anchor in the form of a myocardial implant stored within the tube and moveable out of the tube for placement

during a surgical procedure; a suture, anchor wire 65, connected to the anchor and continuous with the body of the anchor, thus leading out toward the back end of the tube 79; and a coil 21 on a front end of a shaft, pin 77, that is translatably disposed within a lumen in said tube, said coil 21 being extendible out of the front end of the tube.

With respect to **claim 59:** Hussein discloses a catheter comprising the following: a flexible and torqueable tube having a front end and a back end inasmuch as the tube is able to be inserted and navigated from an incision to a surgical site in the heart; a handle 78 attached adjacent to the back end of the tube; a hollow needle 70 within the tube and having a piercing tip 73 extendible out of the front end of the tube;
one anchor in the form of a myocardial implant within the needle 70 on pin 77 between the tip 73 and the portion adjacent handle 78, with the anchor moveable out of the piercing tip 73 of the needle; an anchor ejector, pin 77, within the needle, a suture, anchor wire 65, connected to the anchor and leading out towards the handle (Figs. 1, 13A); a needle control in the form of a key 80 on the handle linked to the needle 70 for moving the needle within the tube by either bringing it into position to lock in place or unlocking, allowing the needle to move on its own; an anchor ejector control on the handle in the collective form of pin 81, spring 82, stop 83 and slot 84 linked to the anchor ejector 77; and a coil 21 on a front end of a shaft that is translatably disposed within a lumen in said tube, said coil being extendible out of the front end of the tube upon insertion into heart wall tissue.

With respect to **claim 60:** Hussein discloses a catheter comprising the following: a flexible tube 79 having a front end and a back endinasmuch as the tube is able to be inserted and navigated from an incision to a surgical site in the heart; a needle 70 within the tube and having a tip 73

extendible out of the front end of the tube; at least one anchor in the form of a myocardial implant positioned within the needle 70 on pin 77 and moveable out of the needle tip for insertion into heart wall tissue during a surgical procedure; a suture in the form of anchor wire 65 connected to one or more of the anchors, and with the suture 65 being continuous with the body of the anchor (Fig. 1) thus extending within the tube towards the back end of the tube; and a coil 21 on a front end of a shaft, pin 77, that is translatably disposed within a lumen in said tube, said coil 21 being extendible out of the front end of the tube.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 2, 3, 5, 47, 48 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussein et al ('993) in view of Madrid et al (U.S. Patent Application Publication No. 2002/058905).

With respect to **claim 2:** Hussein does not disclose that the tube is formed of a braided wire. Madrid discloses that catheters formed of braided stainless steel are well known in the art, and such steel wire braided catheters are biocompatible. Therefore it would be obvious to one of ordinary skill in the art to modify the device of Hussein such that the tube is formed of braided stainless steel as disclosed by Madrid with a reasonable expectation of success to provide a biocompatible delivery device. ('905, 0046)

With respect to **claim 3:** Hussein does not disclose that the tube is formed of a braided wire. Madrid discloses that catheters formed of braided stainless steel are well known in the art, and such steel wire braided catheters are biocompatible. Such braided configurations also define slots that are diamond-shaped and it is examiner's position that the major axis of those diamond-shaped slots is perpendicular to the longitudinal axis, i.e. the slots are disposed substantially perpendicular to a longitudinal axis of the tube. It would be obvious to one of ordinary skill in the art to modify the device of Hussein such that the tube is formed of braided stainless steel as disclosed by Madrid with a reasonable expectation of success to provide a flexible and biocompatible delivery device. ('905, 0046)

With respect to **claim 5:** The slot density of the device of Hussein as modified by Madrid is increased near a distal end of the tube due to bending of the tube nearest the handle which causes a compression of the braid threads toward one another in a smaller area, thus increasing slot density.

With respect to **claim 47:** It is the examiner's position that the tube of Hussein is torqueable because it is flexible enough to be used to navigate from an incision to a surgical site in the heart wall.

Hussein does not disclose that the tube is formed of a braided wire. Madrid discloses that catheters formed of braided stainless steel are well known in the art, and such steel wire braided catheters are biocompatible. Therefore it would be obvious to one of ordinary skill in the art to modify the device of Hussein such that the tube is formed of braided stainless steel as disclosed by Madrid with a reasonable expectation of success to provide a biocompatible delivery device. (‘905, 0046)

With respect to **claim 48:** Hussein does not disclose that the tube is formed of a braided wire. Madrid discloses that catheters formed of braided stainless steel are well known in the art, and such steel wire braided catheters are biocompatible. Such braided configurations also define slots that are diamond-shaped and it is examiner’s position that the major axis of those diamond-shaped slots is perpendicular to the longitudinal axis, i.e. the slots are disposed substantially perpendicular to a longitudinal axis of the tube. It would be obvious to one of ordinary skill in the art to modify the device of Hussein such that the tube is formed of braided stainless steel as disclosed by Madrid with a reasonable expectation of success to provide a flexible and biocompatible delivery device. (‘905, 0046) The limitation "to increase the flexibility of the tube” is a functional limitation that bears little patentable weight. The device of Hussein as modified by Madrid meets the limitations as to a braided tube with slots extending substantially perpendicular to a longitudinal axis of the tube and thus the flexibility of the tube is necessarily increased.

With respect to **claim 56:** Hussein does not disclose that the tube has through slots to increase the flexibility of the tube. Madrid discloses that catheters formed of braided stainless steel are well known in the art, and such steel wire braided catheters are biocompatible. Such braided configurations also define slots that are diamond-shaped and it is examiner's position that the major axis of those diamond-shaped slots is perpendicular to the longitudinal axis, i.e. the slots are disposed substantially perpendicular to a longitudinal axis of the tube. It would be obvious to one of ordinary skill in the art to modify the device of Hussein such that the tube is formed of braided stainless steel as disclosed by Madrid with a reasonable expectation of success to provide a flexible and biocompatible delivery device. ('905, 0046) The limitation "to increase the flexibility of the tube" is a functional limitation that bears little patentable weight. The device of Hussein as modified by Madrid meets the limitations as to a braided tube with slots extending substantially perpendicular to a longitudinal axis of the tube and thus the flexibility of the tube is necessarily increased.

7. Claims 12 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussein et al ('993) in view of Hayhurst (U.S. Patent No. 6,656,182).

With respect to **claim 12:** Hussein discloses a means for pushing the anchor 18 out of a distal end of needle 70 however such means does not further comprise a push rod translatably disposed within the needle and adapted to push the anchor 18 out of a distal end of the needle 70. Hayhurst teaches that the instant needle comprises a push rod in the form of hollow needle 16 translatably disposed within the needle and adapted to push an anchor 10 out of a distal end 26 of the needle 14. Since the device of Hayhurst seeks to solve a similar problem in the art to that with which applicant is concerned (i.e. deliver a suture and anchor to a tissue site for a

surgical procedure), and the push rod accomplishes the same result as the spring and needle tip mechanism disclosed by Hussein ('993, Col. 5, lines 50-64), it would be obvious to one of ordinary skill in the art to modify the device of Hussein such that the delivery catheter further comprises a push rod translatably disposed within a needle to push the anchor out of the distal end of the needle as taught by Hayhurst with a reasonable expectation of success.

With respect to **claim 52:** Hussein discloses a means for pushing the anchor 18 out of a distal end of needle 70 however such means does not further comprise a push rod longitudinally movable within the needle for pushing the anchor 18 out of a distal end of the needle 70. Hayhurst teaches that the instant needle comprises a push rod in the form of hollow needle 16 translatably disposed within the needle and adapted to push an anchor 10 out of a distal end 26 of the needle 14. Since the device of Hayhurst seeks to solve a similar problem in the art to that with which applicant is concerned (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), and the push rod accomplishes the same result as the spring and needle tip mechanism disclosed by Hussein ('993, Col. 5, lines 50-64), it would be obvious to one of ordinary skill in the art to modify the device of Hussein such that the delivery catheter further comprises a push rod longitudinally movable within the needle to push the anchor out of the distal end of the needle as taught by Hayhurst with a reasonable expectation of success.

With respect to **claim 58:** Hussein discloses a means for pushing the anchor 18 out of a distal end of needle 70 however such means does not further comprise a push rod longitudinally movable within the needle for pushing the anchor 18 out of a distal end of the needle 70. Hayhurst teaches that the instant needle comprises a push rod in the form of hollow needle 16 translatably disposed within the needle and adapted to push an anchor 10 out of a distal end 26 of the needle 14. Since the device of Hayhurst seeks to solve a similar problem in the art to that

with which applicant is concerned (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), and the push rod accomplishes the same result as the spring and needle tip mechanism disclosed by Hussein (‘993, Col. 5, lines 50-64), it would be obvious to one of ordinary skill in the art to modify the device of Hussein such that the delivery catheter further comprises a push rod longitudinally movable within the needle to push the anchor out of the distal end of the needle as taught by Hayhurst with a reasonable expectation of success.

8. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hussein et al ('993) view of Iwami et al (U.S. Patent Application Publication No. 2002/0087098).

With respect to **claim 54:** Hussein does not disclose that the tube has a coating of Iluorine resins. Iwami teaches coating a catheter with fluorine resin to act as a location marker for observation of the progress of the tube during endoscopy while the tube is in the body. Thus it would be obvious to one of ordinary skill in the art to modify the device of Hussein such that the instant tube has a coating of fluorine resin as taught by Iwami to provide a mark on the tube to allow observation of the tube’s progress during an endoscopy procedure with otherwise limited visibility. (‘098, ¶¶0026,0034,0035,0102)

Allowable Subject Matter

9. Claim 4 is still objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761